

Case No. 22-16770

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATURAL GROCERS, CITIZENS FOR GMO LABELING, LABEL GMOS,
RURAL VERMONT, GOOD EARTH NATURAL FOODS, PUGET
CONSUMERS CO-OP, NATIONAL ORGANIC COALITION, AND CENTER
FOR FOOD SAFETY

Plaintiffs-Appellants,

v.

THOMAS J. VILSACK, *et al.*,

Defendants-Appellees,

On Appeal from the United States District Court, Northern District of California
Case No. 20-5151 (Hon. Judge James Donato)

NATURAL GROCERS, ET AL. PLAINTIFFS-APPELLANTS' REPLY

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GLOSSARY

AMS	Agriculture Management Service
APA	Administrative Procedure Act
BE	Bioengineered
DNA	Deoxyribonucleic acid
EPA	Environmental Protection Agency
FDA	Food & Drug Administration
GE	Genetically Engineered
GMO	Genetically Modified Organism
LOD	Limit of Detection
PCR	Polymerase Chain Reaction
QR Code	Quick Response Code
rDNA	Recombinant Deoxyribonucleic acid
USDA	United States Department of Agriculture

INTRODUCTION AND SUMMARY OF ARGUMENT

Appellee USDA's brief is more telling for what it leaves out than what it offers. USDA does not deny the plain language of the National Bioengineered Food Disclosure Act (Disclosure Act or Act) mandates disclosure for all foods that "contain" or "may contain" bioengineered material, and that nothing in the Act mentions "detectability" as a prerequisite for disclosure. And it does not deny that the Act expressly anticipates, applies, and allows for "similar terms" to bioengineered, or that there is no mystery about which similar terms Congress had in mind, namely the much more familiar, used-for-decades genetically engineered (GE) and genetically modified (GMO). Most importantly, Appellees fail to support with record evidence both their rule's "undetectable" exemption and their miserly terminology limitation.

First, regarding its "detectability" exemption, nothing in the record supports USDA's stance that refined bioengineered foods do not still contain bioengineered material. Instead, the record repeatedly confirms that while some older, less sensitive tests cannot detect bioengineered material, newer ones can. And here's perhaps the key point: detectability testing is not capable of confirming foods do not "contain" genetic material because it is a scientific inquiry that can only confirm an amount

falls below a certain limit. That rule pathway simply does not implement the statute's directive.

At the end of the day, contains means *contains*; it does not mean, *sometimes not detectable*. USDA's arbitrary rulemaking means that the *very same* bioengineered food could either require disclosure or not, depending on the test used by the manufacturer. This is prototypical arbitrary agency action. USDA's conjuring of an extra-statutory loophole—indeed, for the *vast majority* of the bioengineered foods—is arbitrary and capricious and must be remanded.

Second, regarding terminology, nothing in the record supports USDA's rationales that the familiar terms GE/GMO would increase confusion and erode consistency. Their brief does not fix this fundamental failing. To pass APA muster, agencies must support their decisions with actual record evidence and make a rational connection between the facts found and the conclusion made. Those basic flaws are glaring here. The record supports the exact opposite conclusion: consumers recognize GE/GMO but not bioengineered, and USDA *knows* consumers will require additional education to address inevitable confusion. And regarding consistency, the Act itself shows Congress disagrees with USDA that “similar terms” would create inconsistency: it uses GE and GMO and specifically allows for

bioengineered *and* “similar terms.” It’s not as if there are some other similar terms to bioengineered. GE and GMO are it; no other terms are used in this space.

Without textual or record support, USDA is left to rely on improper post-hoc rationalizations. On detectability, despite never once mentioning it during rulemaking, USDA assures this Court that exempting “undetectable” bioengineered ingredients somehow “determine[s] the amounts of a bioengineered substance that may be present in food ... for the food *to be* a bioengineered food,” 7 U.S.C. § 1639b(b)(2)(B) (emphasis added), a nonsensical claim considering the provision is about accidental contamination not intentional use, that detectability is not an “amount,” and that USDA does *not* consider refined foods “to be ... bioengineered food[s],” *id.* And as for terminology, USDA claims for the first time here that bioengineered covers a different scope of technology than GE/GMO, again despite being asked this exact question during rulemaking and repeatedly *refusing* to differentiate the terms GE/GMO and bioengineered with respect to the technologies they designate.

All this, and USDA still insists that it is *Appellants* that “disregard the nature of arbitrary and capricious review.” ECF 39 at 20. But Appellants’ claims sound in quintessential arbitrary and capricious review bedrock: USDA provides rationales directly contrary to record evidence, *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State*

Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (rules “arbitrary and capricious if the agency has ... offered an explanation for its decision that runs counter to the evidence before the agency[.]”); supplies post-hoc rationalizations, *id.* (“[C]ourts may not accept appellate counsel’s post-hoc rationalizations[.]”); capriciously creates an uneven playing field on which the same product would be labeled or not based on the manufacturer’s choice of detection method, an extra-statutory factor, *id.* (reliance on “factors which Congress has not intended it to consider”); and fails to consider recent studies showing refined foods still contain detectable genetic material, *District Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 57 (D.C. Cir. 2015) (“If an agency fails to examine the relevant data ... it has failed to comply with the APA.”). USDA admits it must draw a “rational connection between the facts found and the choice made.” ECF 39 at 22, 32 (citing *State Farm*, 463 U.S. at 43). That is missing here.

Finally, regarding vacatur, USDA continues the theme and cannot come up with *a single record citation* for its contention that disruptive consequences of vacating the standalone QR code and text message disclosure options outweigh its acknowledged, undisputed, and un-appealed “substantial error.” Its failure to meet its evidentiary burden shows vacatur was proper here. Instead, Appellees improperly conflate the default, normal remedy of vacatur with the very different injunction standard.

Accordingly, Appellants respectfully request this Court vacate the rule, and remand to USDA to conduct further proceedings consistent with the Court's decision.

ARGUMENT

I. THE RULEMAKING'S TREATMENT OF HIGHLY REFINED BIOENGINEERED FOOD WAS ARBITRARY AND CAPRICIOUS

According to USDA's "detectability-equals-contains" theory, foods derived in whole or in part from genetically modified crops are exempt from disclosure if a test fails to detect the food's bioengineered content. ECF 39 at 25-26, 28-29. That decision is arbitrary and capricious and contrary to the record for three reasons. First, no test for bioengineered material can demonstrate its absence, only that it is not present in amounts above the test's limit of detection: "not detectable" never proves "does not contain." Second, because tests differ greatly in sensitivity, the very same food product would sometimes require labeling and sometimes not, wholly depending on the manufacturer's choice of test, creating an uneven playing field for producers and depriving consumers of the uniform, consistent information they deserve and that Congress intended. And third, sensitive DNA testing reveals that even highly processed bioengineered foods (vegetable oils, sugars) do in fact "contain" modified genetic material, yet they can nevertheless escape disclosure.

These outcomes are quintessentially arbitrary, in violation of the APA. None of the Appellees' arguments change this conclusion.

A. Detectability Testing Does Not Examine Whether Foods Contain Bioengineered Material

First, two of three rule pathways¹ to avoid disclosure rely on a testing method's failure to detect bioengineered material; they are thus arbitrary and capricious because those pathways do not and cannot warrant a conclusion a product does not "contain" modified genetic material. (Fortunately, the rulemaking provides a third and valid pathway to avoid disclosure, *infra* p.18.)

As the record explains, "competent scientists know that it is not possible" for a test to confirm the absence of bioengineered material in foods. 1-FER-108 (American Phytopathological Society comments, professional association for plant pathologists). Instead, the test can only demonstrate the bioengineered material is below the test's *limit of detection*.² For example, a test with a limit of detection (LOD)

¹ 7 C.F.R. § 66.9(a)(3) (2023) (allowing entities to "confirm the absence of modified genetic material" through testing to evade disclosure); *id.* § 66.9(a)(2) (use of such testing to validate a refinement process as rendering GE material undetectable). ECF 37 at 6 ("AMS allowed an exemption for only those highly refined food products in which there is a demonstrable absence of detectable genetic material.").

² A limit of detection is the "minimum amount or concentration of the analyte in a test sample which can be detected reliably but not necessarily quantified, as demonstrated by a collaborative trial or other appropriate validation." 2-FER-344.

of 0.1% can detect one GM corn kernel amidst 1,000 otherwise conventional corn grains but will not detect it if mixed with 10,000 kernels, which requires a 0.01% LOD test. 2-ER-301. However, *neither these nor any tests* can do what these disclosure-avoidance pathways demand, which is to “confirm *the absence* of modified genetic material,” 7 § C.F.R. 66.9 (a)(3), or show a food “*does not contain*” it. ECF 39 at 23.

The problem is insuperable: tests that by their nature can only show *paucity* of bioengineered material *cannot demonstrate absence*,³ which does not admit of degree. This is why competent scientists never infer absence or non-existence from negative polymerase chain reaction (PCR) results. *See, e.g.,* 1-IntvSER-225 (non-detection of DNA in sugar described as “below the limit of detection,” not absence). Sister agency EPA also understands chemical test values “below the limit of detection (LOD)” do not signify absence, and for this very reason replaces such “below the LOD” results with “half the LOD” to account for the likely presence of the chemical at undetectable levels.⁴

³ *Absence*, Merriam-Webster, at <https://www.merriam-webster.com/dictionary/absence> (“The state or condition in which something ... is not present or does not exist”).

⁴ EPA, *Methods of Dealing with Values Below the Limit of Detection*, https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=62970&Lab=NE RL; *Safer Chemicals, Healthy Fams. v. U.S. EPA*, 943 F.3d 397, 420 n.13 (9th Cir. 2019) (permitting judicial notice of government documents).

Appellees simultaneously admit and deny highly refined foods contain (modified) DNA, ignoring the contradiction. USDA paradoxically adduces the fact that current tests “can now detect even miniscule traces of [modified] genetic material” as evidence that company tests “establish that their foods do not contain” it. ECF 39 at 32. Intervenors claim that refining “eliminates all genetic material” from beet sugar, but nevertheless renders it only “a 99.9% pure sugar product” (ECF 37 at 12, 14), meaning 0.1% are “undesired substances, including DNA and protein.” 83 Fed. Reg. 65,814, 65,834 (Dec. 21, 2018). In short, Appellees mischaracterize the nature of the scientific inquiry when they claim that negative test results demonstrate the absence of modified genetic material in a food refined from a bioengineered source, rather than its presence at levels undetectable by a given test.

B. USDA’s Failure to Set a Standard Detection Limit Creates Arbitrary Results

Second and relatedly, even under USDA’s erroneous “undetectable-equals-does-not-contain” rubric, the rule’s two testing-based pathways are arbitrary and capricious because they do not set any standard limit of detection.

The “uniform disclosure standard” promised by USDA, 83 Fed. Reg. at 65,836, is impossible to achieve without establishing actual uniform standards regarding bioengineered material content and tests to detect it. USDA refers to “testing” generically, as if all PCR tests were the same, but current tests have a wide

range of sensitivities, as expressed by their limits of detection (LODs). While an LOD of 0.1 percent was once common, 2-FER-215-224, scientists recently developed PCR screening with over ten-fold greater sensitivity: < 0.01 percent for GE corn products. 2-FER-306-314. Current methods have limits of detection all the way to 0.005 percent, or 20 times more sensitive than tests not long ago. 1-FER-4-12.

As a result, without a uniform detection limit, two *identical* bioengineered food products containing 0.05% GE material—one tested with a method whose limit of detection is 0.005%, and another with a test LOD of 0.1%—would either require labeling or not under the rule. This is the outcome of arbitrary agency action and contrary to the statute’s plain language and intent of meaningfully informing consumers.⁵

It is arbitrary to apply “detectability,” as USDA does, *e.g.* 7 C.F.R. § 66.9, without reference to sensitivity; a test’s ability to detect is in large part determined by its sensitivity, its LOD. It’s like traffic police giving speeding tickets without reference to a speed limit. There is no speeding without a numerical limit or detectability without a limit of detection.

⁵ *E.g., Cnty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1022 (D.C. Cir. 1999) (“A long line of precedent has established that an agency action is arbitrary when the agency offer[s] insufficient reasons for treating similar situations differently.”); *Muwekma Ohlone Tribe v. Salazar*, 708 F.3d 209, 216 (D.C. Cir. 2013) (same).

To the extent the rule grapples with the issue, its reasoning is circular: § 66.9(c)(4) requires a “sufficiently sensitive” test—*sufficient for what?*—“for the purposes of the detectability requirements of this part.” No other section provides a “purpose” to guide choice; instead, companies are told only “testing” should be “appropriate to the specific food” and “appropriate (fit for purpose).” 7 C.F.R. § 66.9(a)(3), (c)(2). USDA’s guidance is similarly vague and conclusory: a “fit for purpose” method is “appropriate (fit for purpose),” and “has appropriate accuracy, precision, robustness, reliability, reproducibility, and range for the entity’s testing needs,” with selection of test sensitivity left to the producer’s “best discretion.”⁶

Neither does USDA’s mantra-like *passim* invocation (ECF 39 at 2, 19, 20, 28, 29, 31, 32, 34) of “scientifically validated” fix the problem. Scientific validation of a test or method has no bearing on test sensitivity. Entities might use a scientifically validated test that is yet so insensitive that it can only quantify bioengineered material that comprises more than 1% of the food. 2-FER-349 (“a quantitative PCR method” with “threshold level of 1%” for GE content).⁷ Further, companies are

⁶ USDA, *Frequently Asked Questions: Guidance on Testing Methods*, at https://www.ams.usda.gov/sites/default/files/media/NBFDS_FAQtestingMethods.pdf (FAQs, #1, #2).

⁷ ECF 39 at 25, 2-SER-37 (detecting rDNA in just 13% and 8% of bioengineered soy and corn products).

under no obligation to follow International Organization for Standardization’s “validated sampling and detection methods to detect rDNA in food products,” as implied by USDA (ECF 39 at 25); the guidance citation is permissive (“should”) and ultimately companies are free to devise their own methods.⁸ Without standardized tests with uniform limits of detection, the rule cannot provide the “mandatory uniform national standard” Congress intended. 83 Fed. Reg. at 65,814.

USDA also mis-frames test sensitivity as purely a future issue (ECF 39 at 33), when *current* tests encompass a wide range of LODs, among which companies may choose using their “best discretion” to suit their “testing needs.” *See supra*. And Appellees are wrong to suggest that “if scientific testing should become even more sensitive in the future, it would generally be incumbent on regulated entities to make use of those tests.” *Id.* USDA cites 7 C.F.R. § 66.9, but as explained above it prescribes zero obligation on companies regarding test sensitivity. Actually, section 66.9(b)(2) ensures entities they *need not update* their methods as more sensitive tests are developed: Once they have validated a refining process, “additional testing is not necessary” to avoid disclosure of bioengineered material “in food subsequently refined through that process,” provided only that the refining process is not changed and records demonstrate that process is validated and used. To avoid switching to a

⁸ USDA *supra* note 6 at FAQ #8.

newer, more sensitive test, an entity need only continue using the same refining process, relying upon the original testing that validated it as yielding a product with “undetectable” rDNA, even when a newer test would uncover that bioengineered material’s presence.

Thus, to finish the prior briefing’s “house containing invisible mold” running analogy (ECF 18 at 43; ECF 39 at 33) USDA’s self-described “sophisticated home inspection” would allow a home seller—knowing there was mold (or here, bioengineered ingredients)—to select their own inspector and an insufficiently sensitive mold test, then sell the house as not containing mold. ECF 39 at 33. Contrary to USDA’s contention, this is not “reasonable.” Instead, the result is arbitrariness, where the very same bioengineered food could either require disclosure or not depending on the test used. This violates basic APA rulemaking standards.

C. The Record Shows Refined Bioengineered Foods Still Contain Bioengineered Material

Third, the rule is also fatally belied by the record evidence showing that even highly processed and refined foods still “contain” bioengineered material. Food processing (e.g., milling, cooking, fermentation, or refining) involves heat and pressure that *fragment* and *degrade* genetic material, rendering it undetectable by

some (but not all) testing methods. 1-FER-175; ECF 39 at 26. However, these foods still *contain* fragmented and/or degraded bioengineered material, no matter the refining process.⁹

USDA admits many highly refined bioengineered foods contain bioengineered material. 83 Fed. Reg. at 65,834 (“one study was able to detect rDNA [i.e. modified genetic material] in refined soybean oil.”); *id.* (“[I]ndustrial processes developed for the refining of sugars and oils effectively eliminate *the majority* of undesired substance, including DNA and protein,” not all); *id.* (“detection of rDNA in raw cane sugar”) (*see infra*); ECF 39 at 32 (conceding sensitive tests “detect even miniscule traces of [modified] genetic material”). Yet they can still arbitrarily avoid disclosure.

Appellees (ECF 39 at 25; ECF 37 at 13) reference studies finding modified DNA “undetectable” but absent any reference to the respective test’s limit of detection. Reliance on these older, less-sensitive studies is misplaced and proves the point: Even one valid study showing a highly refined product contains modified genetic material trumps all less sensitive tests unable to detect it. To apply the mold

⁹ As applied to DNA, “degrade” and “fragment” are both defined as breaking apart into segments that are still recognized as DNA. *E.g.*, 3-ER-684 (“DNA samples with traces of GMO material and degraded DNA due to food processing”); 3-ER-689 (“Degraded DNA in the [GMO] noodle sample” and “fragment size of the degraded DNA....”).

analogy: the positive finding of one sensitive test is not dismissed (outweighed) by ten negative results of less sensitive tests. Thus, the fact that “real-time PCR assays proved that it is possible to detect and quantify genetically modified” material in “fully refined soybean oil” derived from bioengineered soybeans is dispositive, superseding studies using less sensitive methods. 1-IntvSER-235.¹⁰ Likewise, it is undisputed that DNA was detected in commercial refined sunflower and corn oils. 4-ER-803-07. That genetic material is detectable in fully refined oils derived from three different crops is again determinative: refined oils made from bioengineered ingredients “contain” the bioengineered material, despite the inability of some tests to detect it.¹¹

The situation with sugar is similar. Intervenors are wrong that “the refining process eliminates all genetic material from” sugar products. ECF 37 at 12. In reality, sensitive PCR testing detected sugar cane DNA in raw sugar, 1-IntvSER-220,

¹⁰ USDA itself referenced this study in the rulemaking. 83 Fed. Reg. at 65,834 n.17.

¹¹ Intervenors dispute Appellants’ reference to a different study highlighting detection of DNA in degummed oil refined from bioengineered soybeans (ECF 37 at 19 n.9) but fail to note the authors highlight “the importance of setting up an adequate traceability system for GM soybeans and derived products” because routine testing of sufficient sensitivity is “not feasible.” 4-ER-811.

which contrary to Intervenor (ECF 37 at 14-15, n.6) is a marketed product.¹²

Intervenor (at 13-14, n.6) mischaracterize a “Japanese study” as implying DNA is not present in sugar beet sugar, rather than it being “difficult to extract *sufficient amounts* of DNA” from it for PCR test purposes (1-IntvSER-244, emphasis added), meaning it supports a contains-but-not-detectable conclusion.

Appellants presented the results of these and similar studies to USDA during the rulemaking without response. Importantly these methods are *not* only in the “future” (ECF 37 at 20; ECF 39 at 33), they were available at the time USDA issued the rule. USDA’s silence speaks volumes: more sensitive variants of PCR testing reveal that exempted refined foods “*contain*” bioengineered material.

II. USDA’S EXCLUSION OF “UNDETECTABLE” BIOENGINEERED INGREDIENTS VIOLATES THE DISCLOSURE ACT

USDA’s rulemaking approach is also contrary to the Disclosure Act, as shown by its plain text, the broader statutory structure, canons of construction, and its procedural history.

¹² One example: “Unrefined raw cane sugar” for sale at: Neighborhood Grocery, <https://www.neighborhood-grocery.com/product-page/old-school-raw-cane-sugar>.

A. Plain Text

First, the statute broadly defines “bioengineering” as any food “that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques.” 7 U.S.C. § 1639(1)(A). Contains, even below a test’s limit of detection, *still means contains*, not whatever USDA wishes it to mean.¹³ Where a term is “neither defined in the statute nor a term of art, we are left to construe it ‘in accordance with its ordinary or natural meaning.’” *S.D. Warren Co. v. Me. Bd. of Env’t Prot.*, 547 U.S. 370, 376 (2006) (citation omitted); *Jam v. Int’l Fin. Corp.*, 586 U.S. 199, 209 (2019) (“[T]he legislative purpose is expressed by the ordinary meaning of the words used”). “Contains” means “to have within,”¹⁴ meaning USDA must disclose foods that have within them bioengineered material (*i.e.*, DNA) that “*has been* modified through in vitro recombinant deoxyribonucleic

¹³ Appellees’ re-definition of “contains” instead recalls Humpty Dumpty in *Alice in Wonderland*: “When I use a word... it means just what I choose it to mean—neither more nor less.” Lewis Carroll, *Through the Looking Glass*, 32 (Public Domain, Project Gutenberg 1991) (1871).

¹⁴ *Contain*, Merriam-Webster, <https://www.merriam-webster.com/dictionary/contain>.

acid (DNA) techniques,” 7 U.S.C. § 1639(1)(A) (emphasis added), whether below the limit of detection, degraded, fragmented, or otherwise.¹⁵

Notably for context this same language appears in other statutes creating food labeling regimes. *E.g.*, 7 U.S.C. § 6505(c)(2) (allowing products that “contain less than 50 percent organically produced ingredients by weight” to display the term “organic” on the ingredient panel without detection requirements). Yet in no other context has USDA, FDA, or any other agency allowed manufacturers to claim foods do not “contain” certain ingredients if they avoid detecting them.

B. Statutory Scheme

Second, the bioengineered food definition must be read in the context of the whole statutory scheme and here Congress further instructed USDA even more broadly, to require disclosure of “any bioengineered food *and* any food that *may be bioengineered*.” 7 U.S.C. § 1639b(a)(1) (emphases added). Reading the Act’s

¹⁵ *E.g.*, *All. for the Wild Rockies v. Petrick*, 68 F.4th 475, 493-95 (9th Cir. 2023) (agency improperly applied rulemaking definition that was “unmoored” and “deviates” from the Congressional text, which “results in a [excluded] covered area beyond what Congress authorized”); *citing Michigan v. EPA*, 576 U.S. 743, 750 (2015) (“[A]gency action is lawful only if it rests on a consideration of the relevant factors”).

provisions together,¹⁶ USDA must require disclosure of all foods that contain or even may contain bioengineered material, including refined and processed bioengineered foods.

By creating its detectability exception, USDA failed this statutory command as well, because as foods without detectable bioengineered material undoubtedly still “may be bioengineered.” *Id.* § 1639b(a)(1). This is because, as explained *supra*, there is no way testing methods can ensure the *absence* of genetic material; it only reveals if material is undetectable below a certain limit, while it “may” remain present.

It is only the third pathway in the rule, 7 C.F.R. § 66.9(a)(1), that can truly exempt entities from disclosing that their products “may be bioengineered.” Source tracing provides adequate confirmation on the absence of GE material in foods, not that GE material is simply below a certain level. This is also why, if a product is certified under the Organic Foods Production Act for example, it does not require a bioengineered disclosure because the *source of ingredients* cannot be genetically modified. 7 U.S.C. § 6524.

Third, statutory context and intent shows that USDA’s detectability inquiry is too crabbed: nothing in the Act indicates that it must only be the *end product* that

¹⁶ Scalia & Garner, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* 167 (Thompson West 2012) (whole text canon).

“contains” detectable genetic material. Undoubtedly, even under their own test, bioengineered processed food products with “undetectable” genetic material *formerly* contained detectable genetic material. 83 Fed. Reg. at 65,833 (“DNA remains relatively intact” in raw agricultural commodities before processing). The requirement for only the *end product* to contain detectable bioengineered material simply nowhere in the statute. Instead, the Act speaks in the past tense when describing the importance of the information provided to consumers. 7 U.S.C. § 1639(1)(A) (defining bioengineered foods to include food that contain “genetic material that *has been modified...*”).

Indeed, if USDA was correct, the Act’s process-based exemption for meat from animals that “consumed feed produced from” a bioengineered source, *id.* § 1639b(b)(2)(A), is surplusage.¹⁷ Meat from livestock fed GE corn or soy does not contain detectable GE material. If Congress intended a disclosure standard based on only final product detectability, it would not have needed to explicitly exempt this category, because it would have already been exempted.¹⁸

¹⁷ Scalia & Garner, *supra* note 16 at 174 (surplusage canon).

¹⁸ The European Union also exempts meat from animals fed GE feed; however, consistent with that, it *does* require disclosure of highly refined foods made with GE ingredients. 3-ER-500-01.

C. USDA's Website List of Bioengineered Foods

USDA argues the “presumption” that foods on the List of Bioengineered Foods¹⁹ “may be bioengineered” covers the Act’s mandate to disclosure foods that “may be bioengineered.” ECF 39 at 27-28. But if anything, this structure renders disclosure *voluntary*, not mandatory. Under it, USDA does not require disclosure even when entities identify sources on the List as bioengineered. ECF 39 at 10; 7 C.F.R. § 66.104(b); 83 Fed. Reg. at 65,818. Rather, if source-tracing records confirm a food contains a bioengineered ingredient on the List, the regulated entity is presented with a choice: it could *either* disclose or use a refining method or detectability testing to exempt itself from disclosure. 7 C.F.R. § 66.102(a); *id.* § 66.104(b).

Thus, if anything, the List again reveals the rule’s arbitrary nature: entities submit records that their products “contain” listed GE ingredients, but that they utilized the regulatory loophole to render them “undetectable” by their method. This is arbitrary and capricious. Especially considering the present degraded

¹⁹ USDA argues the list is a “safety net” for consumers (ECF 39 at 17) but it does *not actually require disclosure for consumers*; it serves only to warn regulated entities that their products may require disclosure so that they can evade it through choosing a refining or testing method. Nothing in the Act mentions such a List.

bioengineered material in refined foods going unlabeled, USDA hardly requires labeling of *all* foods that “may be bioengineered.”

D. Bioengineered Disclosure for an Amount of Accidental Contamination

Allowing manufacturers to “prove” a food *is not bioengineered* by showing the degraded bioengineered material is undetectable does not “determine the *amounts* of a bioengineered substance that may be present in food ... for the food *to be* a bioengineered food.” 7 U.S.C. § 1639b(b)(2)(B) (emphases added). While making newfound reliance, USDA does not attempt to explain the connection to this disparate Act provision, erroneously applied by the district court. Nor could it: this provision does not apply here.

First, the provision is about what is nonetheless included/required to be labeled because of *accidental* use of bioengineered materials, not *intentional* use: throughout the rulemaking, USDA directly correlated its authority under 7 U.S.C. § 1639b(b)(2)(B) to its regulation under 7 C.F.R. § 66.5(c), establishing a five percent threshold for contamination from “*inadvertent* or technically unavoidable” material above which a “food [is] considered a bioengineered food.” 7 C.F.R. § 66.5(c) (emphasis added); 7 C.F.R. § 66.1 (excluding “[a]n incidental additive . . . at an insignificant level and that does not have any technical or functional effect in the

food.”). As USDA understood in the rulemaking, this Act provision allows unintentional contamination with bioengineered content, as can happen through crop cross-pollination, seed mixing, weather, or other unintentional events throughout food production and processing. *See, e.g., Center for Food Safety v. Vilsack*, 2009 WL 3047227, at *7-9 (N.D. Cal. 2009) (discussing cross-contamination of GE sugar beets with organic and conventional crops); *Geertson Seed Farms v. Johanns*, 2007 WL 518624, at *4-5 (N.D. Cal. 2007) (similar).

In fact, USDA specifically *rejected* an option in the proposed rule that would have interpreted this provision to allow regulated entities to *intentionally* use GE ingredients up to the threshold amount. 83 Fed. Reg. at 65,850; *id.* at 65,824 (provision does not “allow for the intentional use of a BE substance without requiring disclosure because the agency believes that allowing entities to avoid disclosing despite the intentional presence of BE substances in food does not provide consumers with the information they desire.”).

Second, USDA did not set an “amount” in creating its detectability exemption. Allowing entities to use older, less sensitive tests or newer, more sensitive tests at their discretion hardly determines an “amount.” In fact, USDA *refused* to even set a limit of detection to standardize testing. *See supra* pp. 9-13. And, even if it had, the statute requires USDA to “determine the amounts of a bioengineered

substance that may be present in food ... for the food *to be a bioengineered food*,” 7 U.S.C. § 1639b(b)(2)(B), not the amount to *exempt* a bioengineered food. The provision is about determining what is included even if accidental, not what is exempted.

Finally, even if *arguendo* this provision could somehow be applied to intentional use, USDA failed to even mention it, let alone rely on it, during rulemaking. It cannot do so now. *State Farm*, 463 U.S. at 50 (“agency’s action must be upheld, if at all, on the basis articulated by the agency itself” during rulemaking, not on post-hoc rationalizations).

E. Legislative History

For every quote USDA cites indicating the Act does not mandate disclosure of highly refined foods, there is a quote indicating it does. ECF 18 at 30-31.²⁰ And critically, the contrary statements cited by Appellees (ECF 39 at 29-30) were made *prior* to USDA General Counsel Prieto’s key congressional testimony. That testimony confirmed USDA’s interpretation it had authority to require labeling of “highly refined oils, sugars, or high fructose corn syrup that have been produced or

²⁰ While the legislative history supports Appellants, the Court also need not consult it considering the Act’s plain text. *Food Marketing Inst. v. Argus Leader Media*, 588 U.S. 427, 436 (2019).

developed from genetic modification techniques.” 162 Cong. Rec. S4994 (daily ed. July 12, 2016).²¹ These assurances, read into the record on July 12, 2016, nearly a week after the Appellee-cited statements, were intended precisely to assuage any such concerns. 162 Cong. Rec. S4994 (daily ed. July 12, 2016); 162 Cong. Rec. S4906, S4845 (daily ed. July 7, 2016); *Id.* (“[T]his bill gives USDA broad authority to label GE products,” including those referenced in Prieto’s letter); 162 Cong. Rec. S4994 (daily ed. July 12, 2016) (Senator Stabenow assuring Senator Leahy). And the bill did *not change on this point* between Prieto’s testimony and the final passage, with Senator Stabenow, one of the Act’s primary drafters, agreeing with Prieto’s views over a year after the Act’s passage. 1-FER-147.

Intervenors point to a Senate Report’s discussion of keeping costs low for manufacturers, preventing market disruptions, and minimizing trade burdens, to characterize the rule as solely a “marketing standard” and support a “detectability” exemption (ECF 37 at 18-24). But the Disclosure Act is primarily an *informational* standard, and nothing in the legislative history ties these secondary goals to this

²¹ Some Appellants and other stakeholders also hoped for more clarity, but again USDA’s interpretation in official testimony after Appellants expressed their concerns was intended to resolve the issue. 162 Cong. Rec. H4835 (daily ed. July 13, 2016) (citing letter submitted July 11, 2016, prior to Prieto’s testimony).

specific question of whether “contains” requires detectability. Even if it did, the record reveals the opposite: USDA itself concluded that exempting foods with “non-detectable” bioengineered material may result in *higher* costs for manufacturers, as compared to simply disclosing all bioengineered foods. 1-FER-126 (finding administrative costs to manufacturers higher overall); 1-FER-128-133 (assessing high costs of testing); 2-ER-296. In fact, numerous food companies pushed for disclosure of “nondetectable” foods specifically to avoid these costs. 2-ER-162-63; 2-ER-220-21; 2-ER-278-79.

Further, USDA responded to Intervenor’s concerns regarding supply chain disruptions from increased price differentials between beet and cane sugar,²² and explained it took this into account in finding *higher* costs to manufacturers from exempting “non-detectable” GE foods. 83 Fed. Reg. at 65,864 (referencing 2-ER-296). Finally, far from burdening trade, the record shows²³ that including all foods

²² Intervenor’s note Hershey switched to non-GE sugar, ECF 37 at 23, but it did so in response to consumer demand, not because of legislation. 2-ER-278-79. Hershey also *supports* the labeling of highly refined foods. *Id.*

²³ The European Union and other U.S. trade partners have long required disclosure of highly refined bioengineered products. 1-FER-2-3 (EU comment: USDA should not burden trading partners with inconsistent labeling standards and should label highly refined foods); 2-ER-271(Unilever: labeling highly refined foods will assist trade because about 60 countries already label them, including the EU, Russia, Turkey, Australia, and Brazil).

would create uniformity with international trade, as required. 7 U.S.C. § 1639c(a) (USDA must apply the Act “in a manner consistent with [U.S.] obligations under international agreements.”).

Intervenors also speculatively claim negative consumer response from disclosing highly refined foods will result in 1) higher costs to manufacturers, and 2) economic harm to farmers as demand for “climate smart” GE crop systems would decrease. ECF 37 at 23. The record shows neither is true: USDA’s market observations, market experiments, and consumer surveys indicate little negative response. 1-FER-115 (assuming a market reaction at the lower end of the spectrum). In fact, USDA estimated the testing/validating costs would be *higher* than the costs of labeling and consumer reaction *combined*, 2-ER-296, and predicted that regulated entities may choose consumer reaction over high testing costs. *Id.*; 1-FER-140-45 (finding mandatory labeling *reduces* consumer opposition to GE foods).

And the record provides that GE crops adversely affect farms and the environment, for instance by increasing overall pesticide use, generating herbicide-resistant superweeds, 2-FER-233-38, and driving monarch butterflies to the brink of extinction, 1-FER-14-15. Biotechnology has not increased crop yield potential, 2-FER-228-32, developed climate-ready crops, 2-FER-262-65, or increased soil carbon sequestration to fight climate change, 2-FER-240-42. Instead, GMOs have helped

drive farm consolidation and reduced adoption of sustainable farming practices, 1-FER-94. These are major reasons consumers want bioengineered food labeled regardless of whether the content is detectable in the final product.

III. THE DISTRICT COURT ERRED IN CONCLUDING USDA LAWFULLY BANNED SIMILAR TERMS

USDA²⁴ also fails to adequately explain its decision to cabin allowed terminology to bioengineered. Instead, it relies on the strawman of mischaracterizing Appellants' argument as claiming the Act mandated use of the terms GE/GMO. Here is Appellants' actual argument: USDA's rulemaking rationales for *not* using the well-known similar terms GE/GMO—to defend against confusion and to ensure consistency—are arbitrary and capricious, contrary to the evidence and the Act. ECF 18 at 49-56; *State Farm*, 463 U.S. at 43. The record shows that for both purported interests the rule's outcome will be opposite: it will *create* confusion and inconsistency.

A. Both of USDA's Rulemaking Rationales are Arbitrary and Capricious

First, USDA's explanation that it chose bioengineered alone to "minimize[e] marketplace confusion" for consumers has zero record support. 83 Fed. Reg. at

²⁴ Intervenor's offer no response. ECF 37.

65,851 (2-SER-55). Numerous studies and comments confirm the opposite: that consumers only recognize GE and GMO and have never heard of “bioengineered” food. 2-ER-186-88; 2-ER-297-300 (e.g., over 600,000 searches for GMO, fewer than 80,000 for “bioengineered,” and *none* for bioengineered or BE food); 3-ER-595-96 (Campbell Soup determining consumers understand GMO, not bioengineered); 2-ER-152-53; 3-ER-504-05; 3-ER-472; 2-ER-259-60 (comments that bioengineered is confusing). This is why USDA previously declared that “using ‘GMO/GE’ is the official approach and the policy approach of our Department as a whole.” 3-ER-558.

USDA’s answering brief makes no argument rebutting these points. In fact, USDA cannot produce *a single record citation* in support, beyond its promise to educate consumers about the new term. ECF 39 at 38. But that promise reveals USDA’s awareness that consumers *would be confused*, not that its decision would “minimize confusion.”

Second, USDA’s explanation that bioengineered would “ensur[e] disclosure consistency” also finds no support in the statute or the record. 83 Fed. Reg. at 65,851 (2-SER-55). Although USDA may think it best to use only one term, Congress did not. 7 U.S.C. § 1639c(c); *id.* § 1639i(b); *id.* § 6524. USDA’s insistence

that Congress intended USDA to use only “bioengineered”²⁵ for “consistency” would mean that Congress engaged in surplusage in also allowing “similar terms,” contrary to the canons of statutory construction.²⁶ It also wrongfully presumes Congress authorized “similar terms” without any awareness of GE/GMO as the prominent, *and only*, similar terms to bioengineered. ECF 18 at 54-55 (record cites of GE/GMO as prominent terminology in policy, industry, agencies, internationally, and in the scientific community); *Abramski v. United States*, 573 U.S. 169, 179 (2014) (Congress does not legislate in a “vacuum.”). Congress knew what it was doing in grouping GE/GMO with bioengineered, and USDA failed to lawfully explain why it did not follow suit.

B. USDA’s New Scope Argument is Both Post-hoc and Meritless

Finally, the Court should disregard USDA’s newly minted rationalization that these terms purportedly cover different scopes. ECF 39 at 35. Agencies must support their actions with a “reasoned basis” in the decision, not later litigation. *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947); *Kisor v. Wilkie*, 588 U.S. 558, 579 (2019) (“[A] court should decline to defer to a ... post-hoc rationalizatio[n] advanced to

²⁵ That Congress allowed the use of “bioengineered” is undisputed and irrelevant (ECF 39 at 34-35); the question presented is whether USDA’s failure to also allow the “similar terms” GE and GMO was arbitrary and capricious, and it was.

²⁶ Scalia & Garner, *supra* note 16 at 174 (canon against surplusage).

defend past agency action against attack.”). During rulemaking USDA explicitly *refused* to decide which modification techniques or technologies it considered “bioengineered” versus “genetically engineered,” stating it was “not making a blanket statement regarding the *scope of technologies* that are covered” by bioengineered versus GE/GMO. 83 Fed. Reg. at 65,835 (emphases added). Further, commenters requested USDA clarify if the rule included newer biotechnologies like gene editing, and USDA refused. *Id.*; cf. ECF 39 at 35-36 (but now claiming bioengineered excludes gene editing). Even USDA’s referenced explanation that “bioengineering and bioengineered food accurately reflected the ... potential technology at issue” describes the technology as *potential* because the agency had not decided what technology it associated with bioengineered. 83 Fed. Reg. at 65,837.

USDA now tries a 180-turn, claiming it has decided bioengineered differs from GE/GMO because it “does not encompass other methods of modifying DNA or modifications that can be achieved through conventional breeding or found in nature.” ECF 39 at 35. But during rulemaking USDA declined to even define “found in nature,” and “conventional breeding,” let alone assign these terms categorically to GE/GMO food but not bioengineered. 83 Fed. Reg. at 65,818 (declining to define “found in nature”); *id.* at 65,838 (declining to define “conventional breeding”).

USDA even specifically admitted it had not considered whether to differentiate the scopes of technology for bioengineered versus GE/GMO, promising to consult with other federal agencies on the issue. 83 Fed. Reg. at 65,819. Notably, *none* of those other agencies differentiate between GE/GMO and bioengineered. *See infra*. USDA’s promise to determine the rule’s scope in the future reveals USDA had not done so yet at the time of rulemaking.

Instead, during rulemaking USDA repeatedly explained it chose bioengineered as adequately covering the “products of technology,” that is, if foods “contain” genetic material that has been modified. 83 Fed. Reg. at 65,819 (“[T]he products of technology, rather than solely the technology itself, should be evaluated to determine whether a food meets the BE food definition.”); *see also id.* at 65,834 (substantially similar statement); 83 Fed. Reg. at 65,835 (definition of bioengineering “focuses on the products of technology, rather than the technology”).²⁷ Following that logic, USDA would then have needed to explain how

²⁷ Nor should this Court rely on a single sentence plucked from a Senate Report. ECF 39 at 36. *Abrego Abrego v. The Dow Chem. Co.*, 443 F.3d 676, 683-84 (9th Cir. 2006) (rejecting reliance on report because the statute was “entirely silent as to the burden of proof on removal. Faced with statutory silence on the ... issue, we presume that Congress is aware of the legal context in which it is legislating.”); *Zedner v. United States*, 547 U.S. 489, 510 (2006) (Scalia, J., concurring) (warning such legislative history use “accustoms us to believing that what is said by a single person in a floor debate or by a committee report represents the view of

the “products of technology, not the technology itself” differ among GE/GMO foods and bioengineered foods. It did not, and nor could it: undoubtedly both genetically modified and bioengineered foods “contain *genetic material* that has been *modified* through in vitro recombinant deoxyribonucleic acid (DNA) techniques.” 7 U.S.C. § 1639(1)(A) (emphases added).

Furthermore, these terms have been synonymous, including in USDA and other government agencies, *for years*. USDA’s subagency FSIS used the terms bioengineered, GE, and GMO interchangeably in its 2016 guidance for meat labeling. 3-ER-597-98. And FDA, like USDA itself elsewhere, *equates* the terms “genetic engineering” and “bioengineering” to both describe “modern biotechnology,” 3-ER-665-79, and encourages the use of not just “not bioengineered,” but also “not genetically engineered,” and “not genetically modified through the use of modern biotechnology.” 3-ER-670-71.

Even in this *very rulemaking*, USDA used GMO on its website until July 2017 (so for the first full year-plus of rulemaking implementation) and submitted to the

Congress as a whole—so that we sometimes even will say (when referring to a floor statement and committee report) that ‘Congress has expressed’ thus-and-so.”). On the question presented here, there is no ambiguity as the statute plainly authorizes USDA to use “similar terms,” and includes GE/GMO in lists throughout the Act. Nowhere does the statute distinguish between GE/GMO and bioengineered.

U.S. Patents and Trademark office an on-package disclosure symbol to be used in this regulatory framework that was “GMO” in a circle. 1-FER-209-10. In May 2017, USDA admitted it “could view” GMO as “similar” due to consumers’ familiarity and the “longstanding” use of GMO by the government and scientific community.

3-ER-566. The agency’s brazen about-face now in claiming the terms are not similar constitutes quintessential arbitrary and capricious decision making. *Organized Vill. of Kake v. USDA*, 795 F.3d 956, 966 (9th Cir. 2015).

IV. THE DISTRICT COURT IMPROPERLY REMANDED WITHOUT VACATUR

USDA fails produce a *single record citation* supporting disruptive consequences from vacatur. That goose egg simply cannot meet the agency’s heavy burden to show why this case is one of the unusual circumstances where equity demands remand without vacatur rather than the default remedy.

As an initial matter, Appellees conflate vacatur with injunctions. ER-105; ECF 37 at 26 (citing injunction cases). But the remedy inquiries are polar opposites: the antithesis of the “extraordinary” remedy of an injunction, the “less drastic” remedy of vacatur, *Monsanto v. Geertson*, 561 U.S. 139, 165-66 (2010), is the presumptive remedy for agency actions held to violate the APA, which flows directly from the APA’s commanding “shall . . . set aside” language, 5 U.S.C. § 706(2). Thus,

properly applied, for decades courts have set forth very limited circumstances for the exceptions. *All. for the Wild Rockies v. USFS*, 907 F.3d 1105, 1121-22 (9th Cir. 2018) (“Presumption of vacatur” unless defendants meet burden showing otherwise). Defendants, not plaintiffs, have the burden to overcome vacatur and should only be found to meet it in “limited,” “rare,” or “unique facts” circumstances that “equity demands.” *Pollinator*, 806 F.3d at 532 (“limited”); *Humane Soc’y v. Locke*, 626 F.3d 1040, 1053 n.7 (9th Cir. 2010) (“rare”); *Regan*, 56 F.4th at 668 n.15 (“unique facts”).²⁸

To evaluate if these limited remand without vacatur circumstances are met, courts assess (1) “the seriousness of the agency’s errors” weighed (2) “against the disruptive consequences of an interim change that may itself be changed.” *Pollinator*, 806 F.3d at 532; *Nat’l Family Farm Coal.*, 960 F.3d at 1144-45. Importantly here, that the “deficiency” prong weighs against remand without vacatur is completely unchallenged: the lower court correctly held USDA’s unlawful allowance of QR code disclosures alone—despite its own study showing them overwhelmingly inaccessible—as a “significant error,” 1-ER-21, a conclusion Appellees do not contest.

²⁸ USDA also makes the breathtaking argument that the APA does not authorize vacatur *at all*, (ECF 39 at 45) but that new and novel position is flatly contrary to decades of unanimous federal court precedent, including the Supreme Court and this Court’s controlling precedent cited *supra*, and should be disregarded.

As a result, on the “disruption” prong USDA should have had to meet a heavy burden to outweigh this admittedly “significant” violation of law and reach the rare result of no vacatur. It came nowhere close, for several reasons.

First, USDA has failed to produce *a single document* of evidentiary support for its contention that disruptive consequences would flow from vacatur. Instead, it nakedly speculates vacatur would impact producers not already applying the other options of on-package text or symbols. ECF 39 at 44. And it argues, against the overwhelming weight of evidence, that ending the electronic link and phone text message forms of disclosure might deprive consumers of information, despite its own contrary record determination: that “consumers would *not* have sufficient access to the bioengineering disclosure through [only] electronic or digital means under ordinary shopping conditions at this time.” 83 Fed. Reg. at 65,814, 65,828.²⁹ Undoubtedly, without these inaccessible options, regulated entities would need to disclose with accessible on-package text or symbols instead.

²⁹ USDA also claims vacatur provides no benefit, but this is neither the proper remedial test nor supported by the record. The court described the error as “significant” because of substantial record evidence finding that standalone QR codes provide insignificant access and that a separate standalone text messaging option does not solve that problem. Thus, vacating the QR code option and separate text message disclosure option would thus provide redress and fulfill Congressional intent.

Second, also without a single evidentiary citation, the district court improperly deferred to USDA's post-hoc litigation position. The court's treatment consisted of two conclusory sentences, referencing USDA's briefing, stating: (1) "*It says that vacatur would disrupt consumer access to bioengineering disclosures,*" and (2) "*It also says that vacatur would disrupt the food industry, which was required to comply with the regulations as of January 1, 2022.*" 1-ER-21 (emphasis added); 1-ER-104-05 (arguing same). The court erred in deferring to USDA's unsupported litigation position on remedy, a context where deference is not warranted because, unlike in the merits, there is no supporting administrative record for the agency's conclusions, which also have already been held unlawful. *Sierra Forest Legacy v. Sherman*, 646 F.3d 1161, 1185-86 (9th Cir. 2011) (explaining the merits/remedy deference difference, noting that deference to agency on remedy is "particularly inappropriate when their conclusions rest on a foundation tainted by procedural error").

Regarding whether some manufacturers would have to change their labels: again, there is no actual evidence of disruption. And if it were enough for an agency to simply argue vacatur would force manufacturers to act differently, courts would rarely if ever vacate. But the proper test and normal result are the *opposite*. E.g., *Nat'l Family Farm Coal.*, 960 F.3d at 1145 (vacating despite acknowledging widespread

economic impacts). To be sure, courts retain some discretion to remand without vacatur, but it is only in rare, defined circumstances in which defendants meet their heavy burden through supportive evidence. “Because the agency says so” speculation cannot be sufficient.

Third, USDA and the district court also err in attempting to reverse the burden, claiming Appellants must prove no disruptive consequences from vacatur. ECF 39 at 44 (“The most that plaintiffs can say is that ‘numerous manufacturers were already opting for on-package text and symbols.’”); 1-ER-21 (deferring to USDA’s concerns and noting “*plaintiffs* have not demonstrated otherwise.”). Again, the lower court misconceived the inquiry: this is not Appellants’ burden. *See supra*. Rather, USDA has the burden to show that this is one of those rare circumstances for a result other than vacatur. *All. for the Wild Rockies*, 907 F.3d at 1121-22.

However, if this Court seeks more information on this score, the record provides ample evidence vacatur would *not* cause significant disruption.³⁰ Major manufacturers began using on-package text and symbols years ago. *See, e.g.*, 2-ER-254 (Mars already changed labels to on-package text); 1-FER-112 (Campbell already began labeling with on-package text). And many other food companies strongly

³⁰ Contrary to the Appellants’ delay insinuations (but notably no claim of actual laches) the case was fully briefed three months after the rulemaking’s effective date of January 2022. 7 C.F.R. § 66.1 (compliance date); ER-27-54.

opposed QR code and text message disclosure options during the comment period.

1-FER-61-62; 1-FER-137-38; 1-FER-105; 1-FER-54; 1-FER-47; 1-FER-89.

Fourth, Intervenor present two citations from a comment requesting extra time to exhaust existing label inventory before complying with the rule. 2-IntvSER-423. The comment then, without references, speculates that failing to do so could result in higher consumer costs from changing labels. 2-IntvSER-429-30.³¹ Again, these concerns are unsubstantiated, but even if supported, the court could have easily alleviated them simply through prospective vacatur. *E.g.*, *Ctr. for Env't Health v. Vilsack*, 2016 WL 3383954, at *10-13 (N.D. Cal. June 20, 2016) (prospectively vacating agency action allowing pesticide-contaminated compost in organic farming but exempting compost purchased until ninety days after the court's decision); *Coal. to Protect Puget Sound Habitat v. U.S. Army Corps. of Eng'rs*, 466 F. Supp. 3d 1217, 1226 (W.D. Wash. 2020) (prospectively vacating a permit). Here, prospective vacatur would prohibit entities from continuing to print labels with standalone QR codes or text message disclosures, while setting a timeline for use of existing inventory.

³¹ Intervenor mischaracterize the second reference as 30,000 products labeled with QR codes that would require reprinting, but the products referenced include *all* QR code disclosures, not only QR codes for bioengineered foods. 2-IntvSER-426.

Finally, USDA erroneously claims vacatur, even if granted, would not actually set aside the QR code option,³² only the phone text message option. Intervenor go even further, insisting courts lack authority to *ever* vacate the QR code option, because Congress mandated it. Both are incorrect.

Congress set forth *lawful* standalone QR codes be an option. But only if USDA found sufficient access based on its study. 7 U.S.C. § 1639b(c)(4). Since based on USDA's own study findings the court held the rule arbitrary and capricious as to QR codes, the Act *does not permit, let alone mandate*, such disclosure be allowed until and unless USDA complies with Congress's mandates of remedying that "significant" failing. That is why the district court remanded *both* sections 66.106 (electronic or digital link disclosure) and 66.108 (text message disclosure) of the regulations for "further consideration in a manner consistent with this order." 1-ER-21. That is why both should also be vacated.

CONCLUSION

For the foregoing reasons, Appellants respectfully request this Court reverse and remand to the district court with instructions to remand to the agency to conduct further proceedings consistent with this Court's decision.

³² Contrary to USDA's mischaracterization (ECF 39 at 43) Appellants have always sought vacatur of the QR codes. 3-SER-249-250; ER146-47.

Respectfully submitted this 18th day of June, 2024.

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